REMARKS

Claims 97, 99, 105-111 are pending in the present application. No claim amendments are made with this response.

Applicants thank Examiner Turner for partly withdrawing previous rejections.

Sequence compliance

The disclosure of the application are objected to, for the reason that there is no copy of a computer readable format of the sequence listing. Applicants hereby submit a letter requesting transfer of the computer readable format from the parent case U.S. App. No. 08/456033.

The undersigned hereby states that the undersigned has reviewed the paper copy of the Sequence Listing as required by 37 CFR 1.821(c), and has reviewed the computer readable form of the Sequence Listing, as required by 37 CFR 1.821(e), and that the content of the paper and computer readable copies for the above-referenced patent application are the same as required by 37 CFR 1.821(f).

Double patenting

Claims 97, 99, 105-111 are rejected for obviousness-type double patenting as being allegedly unpatentable over claims 1-8 of U.S. Pat. No. 6,288,031.

Without conceding to the correctness of the rejection, Applicants hereby submit a suitable terminal disclaimer. In view of the terminal disclaimer, Applicants submit that the rejection for this reason is now moot.

Rejections under 35 U.S.C. §112

Claims 97, 99, 105-111 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner alleged that the amendment introducing "at risk of such cell death" as a narrowing limitation with no support, and new matter.

Applicants respectfully traverse. The support for this description can be found throughout the specification, for example, and in particular, at page 12, lines 23 to 30; page 71, lines 29 to 32; but also, among other places, page 9, lines 8 to 12; page 13, lines 12 to 15; page 42, lines 6 to 17; page 44, lines 3 to 6 and lines 21 to 29; page 70, line 16 to page 72 line 4 (Example 3); and page 75, lines 22 to 30. See, for example, page 12, lines 18 to 30 ("The morphogens described herein also are useful for enhancing survival of neuronal cells at risk of dying . . . Non-mitotic neurons are at risk of dying as a result of a neuropathy or other cellular dysfunction of a neuron or glial cell inducing cell death, or following a chemical or mechanical lesion to the cell or its surrounding tissue"). Accordingly, Applicants submit that there was no new matter introduced by the previous amendment, and the amendment is supported amply by the specification. Applicants respectfully request this ground of rejection be withdrawn.

Claims 97, 99, 105-111 are also rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse, and submit that one skilled in the art at the time of filing of this application would not have any problem understanding the phrase "at risk of such cell death" nor identifying what cells are at risk of dying. See, for example, Lassmann, 1996, Behav. Brain. Res. 78(1):9-14, the abstract of which is attached (Exhibit A). Applicants also direct the Examiner's attention to page 3, lines 1 to 12 of the specification, which describes how chemical and mechanical trauma, and neuropathies induced by various insult to the neuronal cells, puts the cells at risk of dying. Further, page 12, line 23 to page 13, line 12 describes various conditions that are cause of, or that concomitantly occur with, neuronal cell death. Also, Applicants described at page 14, line 16 to page 15, line 12, how cells are at risk of dying when subjected to injury. Thus, Applicants submit that the specification gives specific guidance with respect to identifying cells at risk of dying, and Applicants presented evidence that those skilled in the art can readily understand the recitation and recognize such cells even (assuming *arguendo*) in the absence of the teachings of present specification. Accordingly, it is respectfully submitted that the rejection under 35 USC §112, second paragraph, should be withdrawn. If the Examiner maintains the rejection, Applicants respectfully request that documentary evidence be supplied to support the Examiner's position with respect to this rejection.

Applicants also submit that the addition of the description "at risk of such cell death" for the cells subject to the method of the invention simply clarifies and does not limit the claim scope from what was originally intended. The methods relate to decreasing neuronal cell death associated with a neuropathy, or associated with chemical or physical injury, *i.e.*, the cells subject to these methods are assumed to be dying at a certain rate from a neuropathy or chemical or physical injury. Such assumption is supported by what was known to one skilled in the art about neuropathies and chemical or physical injury, as described in the specification, at the time of the filing of this application. Therefore, the phrase "at risk of such cell death" is merely descriptive, and not narrowing.

In view of the above remarks, Applicants believe the pending application is in condition for allowance. A favorable consideration for allowance is requested.

Applicant believes no fee is due with this response other than the $130.00 for filing of the terminal disclaimer. However, if an additional fee is due, please charge our Deposit Account No. 18-1945, under Order No. JJJ-P06-504 from which the undersigned is authorized to draw.

Dated: May 17, 2005

Respectfully submitted,

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Limits: **Publication Date from 1995/01/01 to 1998/01/01**

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1: Behav Brain Res. 1996 Jun;78(1):9-14.

Related Articles, Links

ELSEVIER FULL-TEXT ARTICLE

Patterns of synaptic and nerve cell pathology in Alzheimer's disease.

Lassmann H.

Research Unit for Experimental Neuropathology, Austrian Academy of Sciences, Vienna, Austria.

Related Resources

Recent neuropathological evidence suggests that synapse pathology is the major correlate of cognitive decline in Alzheimer's disease (AD) patients, but also in other dementia syndromes. We suggest that synapse loss in AD-patients mainly reflects neuronal destruction in other iso- and allocortical areas as well as in brain stem nuclei. In addition an impaired compensatory synaptogenesis may contribute to the reduction in synaptic connectivity. The patterns of cell death in AD-brains determined by analysis of DNA-fragmentation in situ revealed significantly higher numbers of dying cells (neurons as well as glia cells) in AD-brains compared to controls. Amyloid deposition as well as neurofibrillary pathology apparently do not induce cell death directly, but may increase the risk of cells to die in response to additional minor metabolic insults. We propose that multiple

pathogenetic factors are involved in the reduction of synaptic connectivity in AD-brains, which finally is reflected in the decline of cognitive functions.

Publication Types:

- Review
- Review, Tutorial

PMID: 8793032 [PubMed - indexed for MEDLINE]
